

# In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS

No. 15-1179V

Filed: May 24, 2016

*****		UNPUBLISHED
MARY RADHAKRISHNAN,	*	
	*	Chief Special Master Nora Beth Dorsey
Petitioner,	*	
	*	Entitlement; Ruling on the Record;
v.	*	Decision Without a Hearing; Lack of a
	*	Medical Opinion; Insufficient Proof of
SECRETARY OF HEALTH	*	Causation; Influenza ("Flu") Vaccine;
AND HUMAN SERVICES,	*	Shoulder Injury Related to Vaccine
	*	Administration ("SIRVA");
Respondent.	*	Special Processing Unit ("SPU")
	*	

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Diana Sedar, Maglio, Christopher and Toale, PA (FL), Sarasota, FL, for petitioner.  
Linda Renzi, U.S. Department of Justice, Washington, DC, for respondent.

### **DECISION**<sup>1</sup>

On October 13, 2015, Mary Radhakrishnan ("petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, et seq.,<sup>2</sup> (the "Vaccine Act" or "Program"). Petitioner alleges that she suffered a shoulder injury casually connected to the influenza vaccination she received in her left arm on October 15, 2012. Petition at ¶¶ 1-4. Petitioner maintains that she "suffered pain in her left shoulder within 24 hours of receiving the [influenza] vaccination." Id. at ¶ 2. She claims that she continues to suffer from this injury. Id. at ¶ 3. The case was assigned to the Special Processing Unit of the Office of Special Masters.

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<sup>1</sup> Because this unpublished decision contains a reasoned explanation for the action in this case, the undersigned intends to post it on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

<sup>2</sup> National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

Under the Vaccine Act, compensation may not be awarded “based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.” § 13(a)(1). Petitioner has failed to file the report of a medical expert, and the medical records do not support petitioner’s claims. For the reasons discussed below, petitioner has failed to demonstrate that she is entitled to compensation. The petition is dismissed for insufficient proof.

## **I. Procedural History**

Petitioner filed her petition without medical records shortly before expiration of the Vaccine Act’s statute of limitations.<sup>3</sup> During the subsequent month, petitioner filed medical records and a statement of completion. See Exhibits 1-5 (ECF Nos. 8, 13); Statement of Completion (ECF No. 14). The initial status conference was held telephonically on December 18, 2015.

During the call, the OSM staff attorney managing this SPU case discussed the lack of support for petitioner’s claim in the medical records which were filed. See Order, issued Dec. 21, 2015, at 1 (ECF No. 15). Petitioner’s counsel indicated she was seeking additional documents to support petitioner’s claim. She requested 30 days to file any additional documents and to determine if petitioner could move forward with her claim. See id.

Instead of any additional proof, petitioner filed a motion for a decision on the record pursuant to Vaccine Rule 8(d).<sup>4</sup> In her motion, petitioner indicated that she “has filed all relevant medical records and affidavits pertaining to this Petition and considers the evidentiary record closed.” Motion for a Decision on the Record, filed Jan. 28, 2016, at ¶ 6. She further indicated that she “will not proffer the opinion of a medical expert in support of vaccine causation of the injury alleged, and consequently elects not to pursue a formal causation hearing with expert witness testimony.” Id. at ¶ 7.

Respondent filed her response less than one month later. Respondent argued that petitioner’s claim should not be compensated and instead, should be dismissed. Response, filed Feb. 16, 2016, at 5 (ECF No. 18).

The matter is now ripe for adjudication.

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<sup>3</sup> Under the Vaccine Act, for a vaccine administered after October 1, 1988, “no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury.” § 16(a)(2). Petitioner received the vaccination alleged as causal on October 15, 2012. See Exhibit 1, filed Oct. 23, 2015 (ECF No. 8). She filed her petition on October 13, 2015.

<sup>4</sup> The Vaccine Rules, which can be found at Appendix B to the Rules of the Court of Federal Claims (“RCFC”), govern all Vaccine Act proceedings. Vaccine Rule 1(a). Under the Vaccine Rules, a special master may “decide a case on the basis of written submissions without conducting an evidentiary hearing.” Vaccine Rule 8(d).

## II. Applicable Legal Standards

Under Section 13(a)(1)(A) of the Act, a petitioner must demonstrate, by a preponderance of the evidence, that all requirements for a petition set forth in section 11(c)(1) have been satisfied. A petitioner may prevail on her claim if the vaccinee for whom she seeks compensation has “sustained, or endured the significant aggravation of any illness, disability, injury, or condition” set forth in the Vaccine Injury Table (the Table). § 11(c)(1)(C)(i). The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. § 14(a). If petitioner establishes that the vaccinee has suffered a “Table Injury,” causation is presumed.

If, however, the vaccinee suffered an injury that either is not listed in the Table or did not occur within the prescribed time frame, petitioner must prove that the administered vaccine caused injury to receive Program compensation on behalf of the vaccinee. § 11(c)(1)(C)(ii) and (iii). In such circumstances, petitioner asserts a “non-Table or [an] off-Table” claim and to prevail, petitioner must prove her claim by preponderant evidence. § 13(a)(1)(A). This standard is “one of . . . simple preponderance, or ‘more probable than not’ causation.” Althen v. Sec’y of Health & Human Servs., 418 F.3d 1274, 1279-80 (Fed. Cir. 2005) (referencing Hellebrand v. Sec’y of Health & Human Servs., 999 F.2d 1565, 1572-73 (Fed. Cir. 1993)). The Federal Circuit has held that to establish an off-Table injury, petitioners must “prove . . . that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” Shyface v. Sec’y of Health & Human Servs., 165 F.3d 1344, 1351 (Fed. Cir. 1999). Id. at 1352. The received vaccine, however, need not be the predominant cause of the injury. Id. at 1351.

The Circuit Court has indicated that petitioners “must show ‘a medical theory causally connecting the vaccination and the injury’” to establish that the vaccine was a substantial factor in bringing about the injury. Shyface, 165 F.3d at 1352-53 (quoting Grant v. Sec’y of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992)). The Circuit Court added that “[t]here must be a ‘logical sequence of cause and effect showing that the vaccination was the reason for the injury.’” Id. The Federal Circuit subsequently reiterated these requirements in its Althen decision. See 418 F.3d at 1278. Althen requires a petitioner

to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Id. All three prongs of Althen must be satisfied. Id.

### III. Evidence Provided by the Medical Records

On October 15, 2012, petitioner visited her primary care physician, R.K. Vishen, M.D., in Orange Park, Florida, complaining of intermittent chest pain and numbness and tingling on her left side for approximately six months. Exhibit 3, filed Oct. 23, 2015, at 5 (ECF No. 8). Petitioner rated her chest pain as three to four on a scale of ten and reported that it usually occurred with exercise or exertion. Id. Dr. Vishen instructed petitioner to keep a diary of her symptoms, to return for re-evaluation, and to call immediately if her symptoms worsened. Id. at 6. Petitioner received the influenza vaccination alleged as causal at this visit. Id.; see also Exhibit 1 (proof of vaccination).

At her follow-up appointment approximately one month later on November 12, 2012, petitioner reported “overall improvement.” Exhibit 3 at 4. She indicated that she was physically active and had just gotten a job as an R.N. (registered nurse). Id. Petitioner made no mention of any shoulder pain or vaccine reaction.

Petitioner sought medical treatment for various unrelated conditions on three instances in 2013-14. She did not report a shoulder injury at any of these visits.

First, petitioner visited Dr. Vishen again on April 22, 2013, complaining of “persistent shortness of breath” (SOB) and upper gastrointestinal (GI) symptoms. Exhibit 3 at 1. She reported elevated blood pressure on one occasion and admitted to being anxious. The numbness and tingling that petitioner reported on October 15, 2012 (the date of vaccination) was included on petitioner’s list of problems, but petitioner did not report any new or reoccurring symptoms. Id. Petitioner’s examination revealed she had normal range of motion. Id. at 2. Dr. Vishen ordered monitoring for six months, a GI consultation, and stress management. Id. at 3.

On October 23, 2013, petitioner visited Ananth Nallapillai, M.D. in Jacksonville, Florida, complaining of sneezing, itchy eyes, a watery nose, and clogged ears for two months. Exhibit 4, filed Nov. 16, 2015, at 7 (ECF No. 13). She reported a history of anemia and B-12 deficiency and no other issues. The results of her examination were normal. Id. at 8. Dr. Nallapillai diagnosed petitioner with post nasal drainage. Id.

Finally, the medical records reveal petitioner saw Daniel Groblewski, M.D., a neurologist, on May 29, 2014, complaining of headaches following a referral from Dr. Nallapillai. Exhibit 4 at 38. During that visit, petitioner reported a current, non-severe headache on her left side which extended to her shoulder. Dr. Groblewski described petitioner as “an otherwise healthy 37-year-old female with a new onset of headaches both intense and mild.” Id. at 39. He ordered imaging and a follow-up appointment in several weeks.

Petitioner did not mention left shoulder pain which she says “started from getting a flu shot to [sic] high up in her arm” until August 24, 2015 (more than 34 months after vaccination). Exhibit 2, filed Oct. 23, 2015, at 2 (ECF No. 8). According to the medical records from that visit, petitioner wished to establish care with a new provider, Terry D. Hashey, D.O. Petitioner had two complaints at that time, dizziness and left shoulder pain. Id. Petitioner’s examination was normal, and Dr. Hashey indicated he would

order copies of petitioner's prior medical records. Id. at 3-4. He asked petitioner to return at a later date for labs and follow-up. Id. at 4. Lab results from testing performed the next day are included in the medical records but there is no evidence of a follow-up appointment. Id. at 5-11.

#### IV. Discussion

According to the medical records filed, prior to receiving the influenza vaccination alleged as causal on October 15, 2015, petitioner reported numbness and tingling on her left side. However, she described this condition as improved one month following vaccination. Petitioner made no mention of left shoulder numbness, tingling, or pain until more than a year and a half later when she complained of a headache consisting of pain which radiated down her left shoulder. Petitioner's description of shoulder pain appears to be associated with a headache, and there is no evidence to suggest any connection to the influenza vaccination she received on October 15, 2012.

The first time petitioner mentions the possibility of an injury following her October 15, 2012 influenza vaccination is August 24, 2015. At that time, petitioner was recalling an event alleged to have occurred more than 34 months earlier. Even after her complaint in 2015, the records do not show that petitioner was ever diagnosed with a shoulder injury related to vaccine administration. No medication or treatment was ever prescribed, and no follow-up treatment was sought. Furthermore, there is no evidence of a follow-up complaint of shoulder pain.

Petitioner claims she suffered left shoulder pain for nearly three years prior to filing her petition but failed to seek medical care until August 15, 2015 (approximately two months before filing the petition in this case). This one entry, almost three years after the fact, which lacks the basic criteria of a shoulder injury related to vaccine administration ("SIRVA") claim,<sup>5</sup> is insufficient to establish vaccine causation.

#### V. Conclusion

This case is not a close call. Petitioner has failed to offer the opinion of a medical expert, and the medical records filed do not support the allegation that she suffered shoulder pain following her October 15, 2012 influenza vaccination. Petitioner has failed to offer preponderant evidence sufficient to satisfy any of the three Althen prongs. Petitioner's allegations are based on her claims alone, unsubstantiated by medical records or by medical opinion.

Petitioner has failed to establish that she is entitled to compensation under the Vaccine Act. **This case is dismissed for insufficient proof.**

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<sup>5</sup> See National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45,132-01, 45136 (July 29, 2015) (to be codified at 42 C.F.R. pt. 100) (proposed addition for SIRVA to the Vaccine Injury Table).

The clerk of the court is directed to enter judgment in accordance with this decision.<sup>6</sup>

**IT IS SO ORDERED.**

**s/Nora Beth Dorsey**

Nora Beth Dorsey  
Chief Special Master

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<sup>6</sup> Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party filing a notice renouncing the right to seek review.